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POSITION PAPER

Quality of life in cardiovascular disease

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Quality of life is still a relatively new term (table 1) that has been used in various ways and is often poorly understood and inappropriately applied. It is a remarkably comprehensive concept: even the narrower formulation of particular interest to doctors (health related quality of life) covers symptoms and all aspects of everyday life.[1–12] Cardiologists have always believed that components of quality of life are important to their patients but they are often sceptical about attempts to quantify them. However, measurement of quality of life is increasingly being required and used in evaluative research and the planning of services. Done badly, it fully deserves scepticism: done well, measures have reliability and validity equal to any physiological or pathological index. This means that measures must be chosen with care for a particular purpose, administered systematically, and interpreted with caution: that it is to say they should be used with as much care as any cardiological measure. It is now essential that cardiologists are aware of the methods, applications, and limitations of quality of life assessment.

Quality of life is multidimensional and there is usually little correlation between effects of illness on symptoms, mood, work, leisure, and family life—with the patterns of consequences depending more upon personality and circumstances. Single global ratings do not do justice to the differential effects on the various domains, and they also conceal the great individual variation in reaction to illness and its treatment. Though most patients show great resilience, a sizeable minority of subjects report considerable medically unnecessary disability which is determined by psychological and social factors.

Quality of life measures are now being used in many ways (table 2). In evaluating treatment we are interested in assessing group change over time, whereas in clinical practice it may be more important to discriminate between patients who are making good progress and those who have problems that might benefit from extra treatment. Assessing quality of life, whether by a routine clinical interview or as part of a clinical trial, depends upon an understanding of theoretical concepts of life, the common consequences of particular illnesses and treatments, and the ways in which standard or newly developed measures can best be applied. Some of the research applications require sophisticated and time consuming procedures: others are more straightforward, requiring much less of the patients' and of doctors' time. Whatever the use, it should now be possible to find or develop measures that are as acceptable and informative as physical assessments—measures with a value that fully justifies the time spent on them. There can now be no excuse for rejecting quality of life assessment as unsatisfactory "soft" information, provided we focus attention on choosing good measures rather than bad ones or inappropriate ones. This paper reviews basic concepts and provides references to standard reading and several clinical examples.

Assessment issues

The choice and use of quality of life measures depends upon knowledge of the range of measures available, of their administration, and of their fundamental characteristics. The measures that are chosen should be appropriate both for the particular purpose and for the resources available for the collection and

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Table 1 Definitions

Health status	A general term covering all aspects of health status: physical, emotional, social
Impairment, disability, and handicap	Three categories defined by WHO. Impairment refers to the physical limitation, disability to the effect on function, and handicap to the consquences for social and everyday activities.
Functional capacity or status or disability	Limitation of everyday activities, often seen as synonymous with quality of life.
Quality of life	A wide ranging term that has defied definition. The conference is concerned with "health related quality of life" (HRQL). Its domains often include physical impairment and symptoms, functional status (physical and emotional), satisfaction, social functioning (work, leisure, social life, marriage, family, sex, etc), financial. It is also necessary to consider the quality of life of relatives and carers.

Table 2 Uses of quality of life measures

Research	Clinical trials of treatment: medical, surgical, educational, etc.
	Epidemiology
	Health services research
Clinical	Selection for specialist surgery, medical care, and other treatment
	Monitor progress and outcome: patients and families
	Selection for rehabilitation and other extra help
	Health promotion
	Clinical audit
Policy	Resource allocation
	Needs assessment

interpretation of data. In any major research study this will require considerable expert advice and adequate pilot studies; specialist help is also useful in more routine applications. We consider in turn the types of instrument, the sources of information, the methods of collecting data, and the fundamental characteristics of the instruments.

TYPES OF INSTRUMENTS

Much cardiological research has used measures of symptoms and of work, but many have been ad hoc unsatisfactory procedures. There has been much less use of standard measures than in some other areas of medical research and practice (such as cancer and arthritis)[13], though the New York Heart Association index of limitation is universally used.[14] There have been few comparisons of the characteristics of different types of measures and of their relation to measures of cardiac function. For example the extent to which changes in measured exercise capacity relate to change in daily activities remains uncertain.[15]

There are two broad classes of measures: generic instruments, which aim to be comprehensive in their cover of the aspects of quality of life and to be applicable to many illness groups, and specific instruments designed for use of a particular medical condition or to assess a particular function.[2 9 10 16] Table 3 lists their advantages and disadvantages. Though standard generic measures (such as the Nottingham Health Profile, Sickness Impact Profile, SF36) are increasingly used in evaluations of drug treatment, cardiovascular research and practice have mainly relied on batteries of specific measures of symptoms, mood, and work status—for example, the extensive research on the treatment of hypertension.[14 17]

Other research, such as recent evaluations of cardiac rehabilitation[18] and of nitrates in the treatment of angina,[19] has used specially developed disease specific instruments. These capture aspects of quality of life that are most important to the particular patient groups and which are covered by very few if any questions in generic instruments, which have been designed for use in more disabled patient groups. They also provide a single outcome measure which simplifies analysis. Preparation of such instruments requires systematic development.[20]

There is inevitably a conflict between the desirability of using an instrument that allows comparison with other illness and patient groups and using specific measures that are more likely to capture the particular implications of an illness or treatment for a homogeneous patient group. There are also conflicts between the ease of using a well known and brief standard instrument and the considerable effort in putting together and administering a battery of specific questions.

SOURCES OF INFORMATION

For largely practical reasons *physicians* have usually been the source of quality of life information, but there is consistent evidence of low reliability and poor agreement between physicians' ratings (which are derived from what patients say and what is observed) and those of the patients themselves. Clear rating instructions and training can improve reliability considerably. However, *the patient* must be the best informant about symptoms, feelings, and the ways in which illness affects what is important to him or her. *Relatives* can give extra information about the patient but there may then be a problem about disagreements. It is best to accept the patient's view and to use interviews with relatives to quantify the often considerable consequences of the patient's illness on the relatives lives.[21] Frequently relatives describe as much emotional distress as patients themselves and a considerable burden of extra care and responsibility, together with restriction at their own interests and satisfactions. This means that the benefits of successful treatment will be underestimated if the impact on the family is not also taken into account. There are, however, several special circumstances in which relatives or other carers can provide the best account of quality of life, for example severely handicapped people, small children, and a very small proportion of psychiatric patients. In assessing children further valuable information can be obtained from teachers.

MEANS OF DATA COLLECTION

Self-report questionnaires are easy to administer, despite practical problems such as literacy, understanding instructions, and having

Table 3 Types of measures

1	**Generic**
	Applicable to a wide variety of groups and cover a wide range of quality of life domains.
(a)	PROFILES
	Single instruments which enable scores of several separate aspects of quality of life (sometimes scores can also be combined into a single index).
(b)	UTILITY MEASURES
	These provide a single index of quality of life varying between full health (1·0) and death (0·0). These can be derived from either an assessment instrument administered to patients or by asking patients to make a single rating of all aspects of their quality of life.
2	**Specific instruments**
(a)	Disease specific (or disease cluster specific). These have been constructed to be especially appropriate to the problems associated with the particular medical condition. The NYHA scale of limitation of activities is an example. There are no standard measures analogous to the Arthritis Impact Measurement Scale extensively used in rheumatology and to several cancer instruments.
(b)	Function specific—as for example, symptoms, satisfaction, mood, pain, cognitive state, activities of daily living (ADL).
(c)	Ad hoc measures designed for a specific study. These need to be carefully designed to meet the research or clinical requirement.
(d)	Batteries of specific measures. It is necessary to consider the problems in analysing multiple outcome measures. Several clinical trials of treatment of hypertension have used this approach.

reading glasses. The main types of question are those requiring yes/no answers, those with scoring on an ordinal scale (Likert scales), and visual analogue scales. Though visual analogue scales are simple and popular, comparative evidence suggests that they are generally less satisfactory than ordinal scales. It is not possible to compare individuals and even with clear anchor points it is impossible to interpret the clinical and practical significance of changes in visual analogue scores. Whatever self-report instrument is chosen, it is essential that it is administered in a standard manner, in suitable circumstances, and after clear instructions have been given by a trained research worker. All too often self-report instruments are poorly presented and constructed and used without proper instructions.

Interviews have considerable advantages and are much more flexible than other procedures. Higher quality information can be collected and they can be used with all patients, including those unable to complete questionnaires. They have practical disadvantages in scoring and in reliable administration which limit their use to circumstances where research workers can be well trained and supervised with careful checks on reliability. Face to face interviews in comfortable and private surroundings are much better than telephone interviews.

Patient diaries are especially useful for changes in episodic symptoms (for example angina) and for frequent assessment of changes in symptom experience. Patient compliance can be a problem, however, and other disadvantages are that focusing attention may increase the frequency or awareness of symptoms. Also the time sample may not be representative and activities not normally done regularly may not arise during a diary period. Holidays and other unusual periods are difficult to rate.

CHARACTERISTICS OF INSTRUMENTS

The characteristics of quality of life measures (table 4) deserve as much attention as do the characteristics of physical procedure.[2 9 10]

Reliability—A fundamental requirement is that an instrument produces the same results in repeated use, (retest reliability). Interview procedures require regular checks of interrater reliability.

Validity is often difficult to establish because quality of life is substantially subjective. It is important to consider the following types of validity:

(a) construct validity—comparison with psychometric properties of other instruments. This may mean examining the agreement of scores with other quality of life procedures or physical investigations. Validity for a particular purpose does not necessarily imply validity for other different applications.

(b) face validity—checking that items cover appropriate topics clearly. This informal procedure means using interviews with patients and discussions with all those involved with treatment to ensure that the instrument covers the whole range of relevant items.

Table 4 Characteristics of measures

Reliability
Validity
Appropriateness
Responsiveness
Weighting and aggregation
Practical design

Appropriateness—Considerable difficulties arise because many instruments are based on what doctors, economists, and other experts have regarded as important and take little account of patients' and of families' views about what is important. In addition, standard generic measures give little opportunity for dealing with wide individual variation in pattern of activity, satisfaction, and expectation. Several psychosocial domains (for example, effects on families) are poorly covered in standard methods, and some aspects such as cognitive function are not included at all. It is necessary to select those measures that are most appropriate for the clinical or research aim, and this will often depend on pilot studies to investigate what is important to patients and families in particular cardiac disorders. For instance, patients with heart failure emphasise fatigue and a difficulty in carrying out everyday activities at a reasonable speed without frequent stops.[15] It is therefore essential that outcome assessment pays particular attention to subjective fatigue and to the speed of activities as well as their extent. This means a specific rating rather than a generic measure. Failure to consider the patient's viewpoint will underestimate disability and may also lead to failure to recognise worthwhile benefits of treatment. Successful heart failure treatment may have only modest demonstrable effects on cardiac function and measured exercise capacity but may enable basic everyday activities to be carried out with much greater ease and satisfaction.

Responsiveness is sensitivity to changes in whatever is being measured. This is a crucial but often neglected requirement. Instruments which are psychometrically well constructed may fail to be sensitive to important changes in the quality of life. Problems with standard instruments which have not been designed especially for the illness or situation being studied include lack of sensitivity to changes in particularly relevant aspects, lack of cover of relevant aspects, and a limited range resulting in ceiling and floor effects.[22] For example, a controlled trial of cardiac rehabilitation used a generic measure to enable comparisons with other patient groups, but also used specific measures that were designed to be especially responsive to the particular benefits that were believed to occur in rehabilitation.[18] A study to look at subjective and objective cognitive impairment after cardiac surgery[23] required elaborate measures of cognitive function (not covered in standard measures) together with a specific mood scale. In the choice of measures for such studies we need to pay as much attention to the psychometric qualities of specific instruments as to generic measures. Measurement of emotional symptoms and well-being is frequently important and small changes (for instance as a side effect of β blockers[24]) are important. A standard mood scale should be chosen with advice from a psychologist. Standard measures are usually skewed towards more severe disability. This may make it difficult to measure satisfactorily improvement after cardiac surgery or other

treatment. Measures may fail to capture the difference between the patient with angina who has to plan daily activities carefully allowing for frequent rests and the same patient who after surgery is able to manage the same activities without anxiety or restriction. Similarly a few questions in a generic measure will not do justice to a change from mild depression to positive well-being.

Weighting and aggregation of individual dimensions and items. Generic measures covering a range of areas of quality of life require methods for combining sub-scores to provide the profile or global score. Such combinations inevitably involve assumptions about what is important in quality of life, assumptions that may not be valid for the particular patients being studied. Awareness of the construction of the instrument should underlie decisions about how to choose an instrument and how to interpret results.

Practical issues—It is essential that instruments are acceptable to patients and that items are readily understood. Self-report questionnaires should be laid out clearly. The instrument should specify the time period covered.

Use of measures in clinical trials and other research

CHOICE OF MEASURES

The extent of quality of life assessment and the choice of measures will depend upon the significance of quality of life as an outcome of the intervention.[3 9 10] We can consider four broad categories of importance which will determine the emphasis on quality of life measures:

Crucial

Physicians cannot make a rational treatment decision without such information, for example the symptomatic treatment of cardiac failure or angina. In these circumstances sophisticated measures will be required together with expert advice in the design and analysis.

Important

Quality of life information is necessary to take an informed clinical decision. An example is the evaluation of medical and surgical treatments of angina in which both expectation of life and symptomatic outcome are important.

Secondary interest

Quality of life is of interest to the physician but unlikely to affect the treatment decision. An example is the evaluation of heart transplant, in which knowledge of the extent and nature of the benefits of quality of life has clinical applications.

Irrelevant

Quality of life measures would have no role in the evaluation of aspirin or thrombolytic agents after myocardial infarction.

Whatever the role of quality of life assessment in patients, investigation of the chosen measures should concentrate on the assessment of areas of the quality of life most relevant to the aims of the clinical trial. The unthinking choice of a short generic measure or of range of specific instruments is unlikely to yield satisfactory results. Many trials make arbitrary assumptions about patients' needs and expectations, but it is often desirable to carry out pilot studies to determine which elements of quality of life are of most importance to patients and their families in relation to their particular treatment. Hypotheses and outcome variables should then be specified in advance. Convenience and brevity are important but should not determine decisions about assessment to an extent that compromises the prospect of conclusive findings. Consideration should be given to the use of change measures (self-report and interview rated) since these are often considerably more sensitive than repetition of state measures at the beginning and the end of the study.

It is essential to be aware that individual instruments are designed for particular uses, in particular research or clinical situations. Instruments may be extremely valuable in some circumstances, but inappropriate in others. Thus many generic instruments include several mood questions but would not be adequate to assess modest but clinically significant mood changes in studies of the side effects of β blockers or of the psychological benefits of cardiac rehabilitation. Frequently a single quality of life procedure is inadequate. For example, generic quality of life measures may not be satisfactory in terms of their validity and responsiveness to answer questions about the specific impact of many treatments. The selection of a well-established core instrument with the addition of extra specific instruments is often the best answer. For example a controlled trial of rehabilitation combined a generic measure, specific instruments, and a utility measure.[18]

There is a need for greater dissemination of information about the role of quality of life measures in cardiology in the way that has been attempted in oncology.[13] This will enable cardiologists both to achieve a better understanding of the role and methods of assessment and also to enable them to seek appropriate specialist help as well as to decide on what new specific instruments may be required for cardiovascular patients.

PRACTICAL ISSUES

Careful planning of practical procedures for administration of measures is necessary, especially in multicentre trials in which it is difficult to maintain quality control. Assessments should be feasible and, as far as possible, combined with clinic or other medical attendances. The period covered by the assessment should be clearly stated. The timing and frequency of testing should relate to the timing of maximum therapeutic impact and to the timing of side effects, and also allow adequate time for changes in life style which may take place relatively slowly.

Whatever instrument is chosen, research workers using quality of life assessment should be appropriately trained in the administration, in providing an explanation to patients, and about suitable circumstances for doing the

assessment. They should give appropriate reassurance about confidentiality, and be able to deal with the problems of patients who have difficulty in completing the self-report. Raters should be blind to the treatment condition.

ANALYSIS AND INTERPRETATION OF FINDINGS

Analysis should cover withdrawals for any reason (including death). Results should be presented both for those completing the programme and on an "intention to treat" basis. Where a range of specific measures have been used, consideration should be given to the use of global scores with well thought out and clearly described aggregation procedures. It may be appropriate to consider a sensitivity analysis which examines the dependence of the results on the weighting scheme that has been used.

MAKING FINDINGS MEANINGFUL

It is important when quality of life assessment is used in clinical trials, or audit, to present the findings in ways that are meaningful to others. Reports of statistically significant changes in mean scores may be of little value to the clinician or the planner. It is also necessary to be aware that fulfilment of expectations is a major element in response to assessment, for example, after a heart transplant subjects may rate their quality of life more highly than do the general population. The assessment procedures need therefore to be clearly described with adequate information to allow the reader to draw conclusions about the extent and significance of the impact of the information on the patients everyday life. Other ways of making quality of life information meaningful include:

- A relevant choice of measures
- Indicating proportions of subjects changing for better or worse
- Inclusion of some definition of a minimal clinically important difference
- Comparison with the impact of other interventions and with other reference groups

Economic assessment of quality of life

The need to make decisions about the allocation of scarce health care resources requires procedures that make the maximum explicit use of extreme data on mortality, morbidity, and quality of life.[25 26] Controversy about the use of quality of life information is focused both on actual techniques used and the ways that they have been interpreted and applied.

Table 5 Definitions

Cost benefit analysis: health outcome and costs expressed in monetary unit
Cost effectiveness: health outcome and costs expressed in non-monetary units
Cost utility: cost effectiveness which includes an expressed preference for health state
QALY: Quality Adjusted Life Year. This combines mortality with a quality of life value or utility

Most attention has been focused on the use of QALYs (Quality Adjusted Life Years). Calculation of the QALY requires quality of life information to be expressed as a single index of utility (0·0–1·0) and then combined with survival data. In the considerable and continuing controversy about the value and use of QALYs criticisms have related to the methods of collection of quality of life information, the transformation of such information into a utility by using the Rosser-Kind or other matrix of utilities, the use of discount rates for future health benefits, and to the final step of combination with survival data.[25 27]

Simple rejection of the QALY approach is no more sensible than total reliance on summary figures. There is no disagreement that lists of QALYs provided without any further information are misleading and should not be used by themselves to compare programmes for resource allocation. Though provision of further information about the derivation of the QALYs for any procedure makes more informed comparisons possible, the argument remains about whether the use of fully documented QALYS has advantages over the presentation of full data without aggregation into a single figure. It has been argued that it is more satisfactory to use QALYs to compare alternatives within a programme rather than compare radically different programmes.

Many of the arguments about the calculation and use of QALYs are highly technical. There are clearly opportunities for improvement in the ways in which they are derived in quality of life information, but there is a particular need for much greater attention to the methods of collecting, quantifying, and using quality of life and other outcome information. Despite these reservations there are good arguments for including a measure of utility alongside other quality of life assessments in major treatment trials.[18]

Resource allocation is concerned with allocation within programmes and between programmes.[25] QALYs have been widely used with varying degrees of understanding of their derivation and meaning. There is a danger that in health care systems under severe financial pressure decisions about priorities will be based on inappropriate use of measures of utility, especially QALYs. Cardiologists need to ensure that analyses and discussion are more widely based and also to consider how other determinants (for example, equity) can be incorporated in decision making and to provide the full information which enables the incorporation of value judgements in a manner that is open to scrutiny. In many situations *needs assessment* which examines incremental changes in services to meet local needs is a more appropriate approach to the evolution of services.

Quality of life in clinical practice

Many treatment decisions in cardiology are partly determined by the physician's assessment of quality of life (table 1). How can

quality of life assessment enable better informed treatment? Standardised quality of life measures are mainly used in research to evaluate changes in patient groups. In clinical practice we are presented with different issues which may require different instruments. We are also concerned with the wide individual variation in quality of life response to physical illness. Some patients are able to continue to lead a remarkably full and satisfying life despite major symptoms and disability, whereas others with much less serious medical problems become gravely handicapped. Between a quarter and a third of those with major physical illness suffer significant "medically unnecessary" effects on quality of life and there is a similar range of consequences for relatives. We need to recognise these patients and monitor their progress. It would be helpful to use standard procedures to identify reliably patients at risk of medically unnecessary disability as early as possible so that they may be given extra help.[2 9] It is uncertain, however to what extent quality of life measures mainly developed for use in clinical trials are suitable for identifying individual clinical problems and for monitoring individual clinical progress over time.

There are a growing number of published reports on screening questionnaires for depression and anxiety, but much less is known about screening for the very varied quality of life problems of importance to patients and their families. It seems unlikely that self-report procedures can ever be more than a guide to the recognition of clinical problems that might benefit from extra intervention. False positives and false negatives are inevitable and there seems to be no substitute for systematic clinical review which is flexible enough to take account of patients' families and particular concerns. Even so, self-report questions might help cardiologists in their clinical recognition of those who may be in need of greater attention.

Standard measures could also be useful in monitoring progress, whether it is long-term drug treatment of angina, recovery from cardiac surgery, pacemaker clinic review, or participation in a cardiac rehabilitation programme that aims to improve quality of life and modify risk factors. Again, we lack suitable disease specific or instruments. There is a need to develop measures for particular situations and to evaluate their use. Cardiology should emulate what has been attempted in oncology and other medical specialties.[13]

Though better quality of life information might be expected to inform clinical judgement, there is little evidence from any area of medicine that physicians' practice is greatly influenced by feedback of information from screening or other procedures.[2 9] This reflects the inadequacies of quality of life measures but also doctors' difficulties knowing how to use such information in planning care. There is little point in recognising problems if this does not lead to conclusions about action. Much greater attention should therefore be given to providing information in a clinically useful format and at the right time. Procedures for management of the individual patient need to be accompanied by feasible methods of audit and clinical management. For example, as cardiac rehabilitation procedures become more widespread, how should they be audited so that we can evaluate their effectiveness? How can rehabilitation units collect quality of life information and use it to direct their resources to those patients most in need of extra help? Considerable attention must be given to the selection of clinically appropriate and useful audit procedures and to the ways in which information is made available and used.

Conclusion

Quality of life is accepted as being important in cardiovascular disease, but there has been widespread scepticism about whether it can be measured in any meaningful manner. Many of the attempts to assess quality of life have relied on conceptually and psychometrically inadequate measures, measures that fail to cover the full impact of heart disease and its treatment on the lives of patients and their families. In contrast, there is now an increasingly wide range of standard measures of quality of life, and an increasingly impressive body of knowledge about the methods of generic and specific measures and the ways in which they should be derived and applied. Such measures are increasingly being used in other areas of medicine, are being expected by funding agencies, and used by planners. We have reached a time when quality of life assessment is both being expected in cardiovascular disease and is realistically possible and worthwhile.

Review of the general literature on quality of life and of use of quality of life assessment in relation to cardiovascular disease suggests basic principles and also conclusions about the ways in which these can be applied to research and clinical practice. We should no longer be prepared to accept ad hoc token assessment but should require high quality measures that have been carefully chosen and properly used. Objections that such measurement is too time consuming, too difficult, or too unreliable, are unacceptable. The use of quality of life measures can be justified in exactly the same manner as measures of cardiac function. Where they are necessary, they should be used properly. In clinical trials this may mean a major investment of expertise; in clinical practice in audit it means the careful use of simple and straightforward procedures. A better understanding and wider use of quality of life assessment will also enable much more sophisticated applications to health service planning.

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